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Application No.: 10/772,703

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Docket No.: 297912002103

REMARKS

The instant application and pending claims have been reviewed in light of the Office Action dated February 9, 2006. Claims 42-53 are pending in the application. Claim 50 has been amended. Applicant submits that no new matter or issues have been introduced.

Objections - Specification

The amendment filed November 28, 2005 with the RCE stands objected to under 35 U.S.C. § 132(a) because it introduces new matter into the disclosure. In particular, claims 50, 52 and 53 allegedly contain added material not supported by the original disclosure. With respect to claim 50, the recitation "greater than the original inner diameter" is supported on p. 15 of the application as originally filed, as discussed more completely below in the response to the rejections under 35 U.S.C. § 112. With respect to claims 52 and 53, the ranges are disclosed on p. 15 and 25 of the application as originally filed and/or in claims 7-10 as originally filed, as discussed more completely below in the response to the rejections under 35 U.S.C. § 112. Thus, Applicant believes that there is support in the application as originally filed for the claim recitation of claims 50, 52 and 53 and therefore, respectfully requests withdrawal of this objection.

Objections - Claims

Claim 50 is objected to because of the informality that "PTFE" is not spelled out in full. In response, Applicant has amended claim 50 to spell out "polytetrafluoroethylene." Claim 53 is objected to under 37 CFR § 1.75(c) as being of improper dependent form for failing to further limit the claim. However, Applicant notes that claim 52 is directed to "the original inner diameter," while claim 53 is directed to "the dilated inner diameter" such that claim 53 further limits the claim from which it depends. Therefore, Applicant respectfully requests withdrawal of these objections.

Claim Rejections - 35 U.S.C. § 112

1. Claims 42 and 50 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, claims 42 and 50 stand rejected allegedly because the specification does not disclose the calculation of radial expansion ratio, in

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instances where it is calculated as 1.0, in such a way as to reasonably convey to one skilled in the art that the inventor had possession at the time the application was filed of the claimed tube with a radial expansion ratio of 1.0. Applicant respectfully traverses this rejection.

The Examiner's rationale for this rejection is reproduced in part below:

"The specification defines Pmax as the highest pressure at which 'the tube retains its structural integrity,' which is the highest pressure at which the 'tube requires the application of an increased inflation pressure before the amount of radial expansion of the tube increases' (page 7, line 32-page 8, line 1). However, once a tube has burst, it cannot be shown that the highest pressure at which the 'tube requires the application of an increased inflation pressure before the amount of radial expansion of the tube increases' is the burst pressure because Applicant does not identify bursting as a loss of structural integrity... Therefore, Applicant's assignment of Pmax as the same pressure as the burst pressure (for example, in Table XI on page 17) is inconsistent with Applicant's definition of Pmax, as defined on pages 7-8 of the specification."

(p. 4, Office Action dated February 9, 2006, underlining added for emphasis).

In view of the underlined section, the Examiner appears to be arguing that because the definition of structural integrity does not specifically mention the bursting of a tube as a loss thereof, it follows that the equations and definitions related thereto (i.e., radial expansion ratio) are indefinite or undefined. However, according to the definition of radial expansion ratio (RER) on p. 7 of the originally filed specification, Pmax and Pburst must be approximately equivalent or equal in order for the value of RER to be 1.0. Indeed, Applicant specifically discusses the case where Pmax equals Pburst in the specification as follows:

"From an endovascular grafting perspective, an RER of 1.0 is an ideal value because the maximum pressure is equal to the burst pressure. This permits the ready dilation of a polytetrafluoroethylene tube without exceeding the maximum pressure. Exceeding the maximum pressure results in the loss of structural integrity."

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The methodology for testing the tubes in the instant specification is discussed, for example, on p. 7, lines 7-18, which includes incremental inflation of a balloon and measuring tubing diameters at selected inflation intervals. At each interval the tube is observed to determine whether Pmax or Pburst has been reached and, if not, the inflation pressure is increased. Pmax can be determined through observation, as discussed in the specification on p. 7, lines 36-38. Specifically, if the tube continues to expand when the amount of inflation pressure decreases, then the tube has lost its structural integrity and the value for Pmax has been discovered. In the case where the tube does not burst at Pmax, continued expansion of the tube occurs until the tube bursts, the pressure reading at the time being the value for Pburst, which is less than Pmax. In such a case, the radial expansion ratio is not equal to 1.0, and therefore not encompassed within the recitation of claims 42 and 50. On the other hand, in the examples in the specification in which Pmax equals Pburst (see e.g., Tables XI, XII and XVII), the radial expansion ratio equals 1.0. Thus, the argument that the definition of radial expansion ratio is indefinite or undefined because Pmax cannot be calculated when Pmax equals Pburst is believed to be untenable.

Therefore, in view of the above, Applicant submits that claim 42 and 50 comply with the written description requirement of 35 U.S.C. § 112, first paragraph, and accordingly requests withdrawal of this rejection.

2. Claims 42, 50, 52 and 53 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the claims stand rejected allegedly because they contain subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession at the time the application was filed. Applicant respectfully traverses this rejection.

With respect to claim 42, the recitation "at least two times said original diameter" is allegedly not supported in the specification because the examples provided show percent dilation at Pburst of 294%, 275% and 252% in Tables XI, XII and XVII, respectively, but not 200% to 250%. With respect to claim 50, the recitation "greater than the original inner diameter" is not supported in

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the specification allegedly for the same reason. With respect to claims 52 and 53, the claimed ranges allegedly are not supported in the specification as originally filed.

In response, Applicant first directs the Examiner's attention to claim 42, which recites, *inter alia*, "wherein said tube is radially dilated from said original inner diameter to an expanded diameter that is at least two times said original inner diameter and is sintered to contract said tube from said expanded diameter to a contracted diameter that is substantially the same as said original inner diameter." This is recitation directed to pre-dilation of the tube as discussed on p. 15, lines 1-26 of the specification as originally filed, which states in part, "the three mm ID sintered porous tube of highly crystalline PTFE polymer is radially pre-dilated by radially dilating the tube to an ID of six millimeters and by then sintering the tube to cause the tube to radially contract to an inner diameter equal to its original inside diameter of three mm" (p. 15, lines 21-26).

Next, Applicant directs the Examiner to claim 50, which recites, *inter alia*, "a radially pre-dilated tube having an original inner diameter and a dilated inner diameter greater than the original inner diameter." This recitation is also supported by the aforementioned section of the specification as originally filed.¹

Finally, Applicant notes that the ranges provided for the "original diameter" of claim 52 and the "dilated diameter" of claim 53 are supported in the aforementioned section and p. 25, lines 33-35 (pre-dilation of PTFE tubing "up to a diameter equal to five time[s] the original diameter"), as well as claims 7-10 as originally filed.

Therefore, in view of the above, Applicant submits that claims 42, 50, 52 and 53 comply with the written description requirement of 35 U.S.C. § 112, first paragraph, and accordingly requests withdrawal of this rejection.

¹ Also see p. 4 of the Amendment dated October 28, 2005, in which it was stated in the Remarks section, "Applicant notes that the definition for "radially pre-dilated" as recited in claim 50 is found on p. 15."

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3. Claims 42, 50 and 53 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses this rejection.

The Examiner, referring to the rejection under 35 U.S.C. § 112, first paragraph, states that claims 42 and 50 are indefinite because the radial expansion ratio of 1.0 cannot be ascertained since Pmax cannot be determined on a balloon that has burst before reaching its Pmax. As discussed above, the Examiner's position appears to be that a loss of structural integrity cannot be determined if the tube bursts, according to the definition of structural integrity (i.e., that loss of structural integrity is determined by continued radial expansion of the tube when inflation pressure is decreased). However, as discussed above, when the tube bursts, the structural integrity of the tube is lost, as one skilled in the art understands. With respect to claim 53, the ranges are provided for different elements, namely original inner diameter (claim 52) and dilated inner diameter (claim 53), as discussed above.

Therefore, in view of the discussion above, Applicant submits that claims 42, 50 and 53 comply with 35 U.S.C. § 112, second paragraph, and accordingly requests withdrawal of this rejection.

Claim Rejections - 35 U.S.C. § 102

Claims 42, 50, 52 and 53 stand rejected under 35 USC §102(b) as being anticipated by Gore (USPN 3,962,153). Applicant respectfully traverses this rejection.

The Examiner states in his reasons for rejection that the recitation of "said tube exhibiting a radial expansion ratio of 1.0" (claim 42) and "the radial expansion ratio of the tube is about 1.0" (claim 50) cannot be treated due to the indefiniteness thereof. However, in view of the discussion above, Applicant submits that these limitation are not indefinite and, further, are not shown or described by Gore. Accordingly, claims 42 and 50 are patentable over Gore because Gore does not show or describe all of the claim limitations therein. Claims 52 and 53 are also patentable because these claims depend from claim 50.

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Claim Rejections - 35 U.S.C. § 103

Claims 43-45 stand rejected under 35 USC §103(a) as being unpatentable over Gore ('153) in view of Gore (USPN 4,187,390). Claims 46-49 and 51 stand rejected under 35 USC §103(a) as being unpatentable over Gore ('153) in view of Marin et al. (USPN 5,618,300). Applicant respectfully traverses these rejections.

Claims 43-49 are dependent on claim 42 and claim 51 is dependent on claim 50, each of which (claims 42 and 50) are believed to be patentable in view of the above. Accordingly, claims 43-49 and 51 are patentable for at least this reason.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 297912002103. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,


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